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14. ABSTRACT
The specific objectives of this research were to adapt a cognitive-behavioral intervention (CBI) for the treatment of anger to specific needs of military personnel returning from hazardous deployments, and to conduct a randomized pilot study providing preliminary data on the adapted intervention. The Phase I open trial showed medium to large pre to post treatment effect sizes for CBI. In phase II, 25 participants were randomized to CBI or the control condition (Supportive Intervention, SI); 23 started treatment. A mean of 8.9 and 9.2 sessions were completed for CBI and SI, respectively. Sixteen participants completed post treatment assessments. CBI improved significantly more than SI on several primary and secondary outcome measures. Between group effects sizes were large, ranging from .78 to 1.22, and improvement was maintained at 3 months post treatment. Treatment conditions did not differ on PTSD symptoms. Ratings of audiotaped CBI treatment sessions showed high levels of therapist adherence. Limitations include the small sample size, the absence of females and the small number of minorities in the sample. Future studies are needed to confirm the efficacy of CBI in larger samples, including adequate numbers of females and minorities.

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PTSD, Anger, Treatment

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Introduction: The long-term goal of the research is to provide an effective intervention for the prevention of secondary and escalating effects of poor anger control associated with trauma-related anger problems. The specific objectives were to 1) adapt an existing evidence-based cognitive-behavioral intervention (CBI) for the treatment of anger to specific needs of military personnel returning from hazardous deployments, and 2) conduct a randomized pilot study providing preliminary data on the efficacy and acceptability of the adapted intervention in this population. The first phase involved administering the adapted CBI to 12 participants, and a supportive intervention (SI) to two participants. Our experience in Phase I led to further revisions of the manual. Goals of the second phase were to conduct a randomized pilot study of 50 male and female participants assigned to receive either CBI or SI.

BODY: Since the last report (March 31 2009) we randomized an additional 5 participants in Phase II. We stopped recruiting participants in November 2009 to allow time for all entered participants to have completed treatment by the end of the study. All post-treatment assessments have been conducted, and all data have been edited and entered. Findings from data analyses of the final sample are described here.

Target Sample

The target sample for both phases of the study was military personnel who have returned from warzone deployment (Iraq or Afghanistan), were exposed to trauma during deployment, and have at least two symptoms of hyperarousal, with one being anger/irritability, associated with at least moderate impairment. Exclusion criteria included current substance dependence psychotic symptoms, current suicidal or homicidal ideation requiring hospitalization, and severe cognitive impairment. Our primary source of recruitment was the Veterans Affairs Medical Center, Providence RI; the majority of the participants had been deployed as part of the Rhode Island National Guard.

Methods

Phase I was an open trial allowing us to gain experience with CBI and the control (SI) and to make revisions to the manual and procedures based on this experience. Phase II was a randomized pilot study.

CBI was adapted from a cognitive behavioral treatment developed by Raymond Novaco, targeted at reducing anger frequency, intensity, and duration, and at moderating the expression of anger (Novaco, 1975). Adaptations included 1) addition of psychoeducation using "Battlemind", developed by researchers at Walter Reed. Throughout the treatment, anger is conceptualized within the context of adaptive function in the warzone that becomes nonadaptive at home; 2) additional emphasis on arousal reduction through relaxation training; 3) including the option of a session involving a spouse or family member focused on psychoeducation; and 4) revisions of the manual organization to facilitate therapist delivery. In addition to psychoeducation and arousal reduction, key elements of CBI include:

- cognitive restructuring (identification and modification of beliefs and interpretations)
- behavioral coping strategies
- inoculation training (exposure through imagery to anger inducing scenes using a hierarchy of individualized scenes)

SI includes the same "Battlemind" psychoeducation and the same arousal reduction strategies as the CBI condition. The rest of the intervention focuses on providing support and using problem solving strategies. Cognitive behavioral interventions other than relaxation strategies are excluded.

Both treatment conditions included up to 14 75-minute individual sessions, and were administered by one of eight Ph.D. level therapists with experience treating veterans with PTSD. Therapists provided both types of treatment. Therapists received one day of didactic training, and ongoing supervision based on audiotapes of sessions. All therapy sessions were audiotaped, and most sessions per case were rated for adherence and competence.

Assessments were conducted prior to beginning treatment, at termination from treatment, and at 3 months following termination of treatment. Measures of anger outcome included the State-Trait Anger Inventory-2 (STAXI-2; Speilberger, 1999), and the Overt Aggression Scale-Modified (OAS-M; Coccaro et al., 1991). The STAXI-2 is a self-report questionnaire with six scales and an Anger Expression Index (AX)—a general indicator of the expression and control of anger. The OAS-M was designed to assess manifestations of aggressive behaviors in outpatients, including the severity, type, and frequency of aggressive behavior. The AX from the STAXI-II and the Aggression subscale from the OAS-M were designated as primary outcome measures. Secondary outcome measures, in addition to the additional STAXI-2 scales and the total OAS-M scale, included functional status as assessed by the Outcomes Questionnaire (OQ; Lambert et al., 2003), and PTSD symptoms measures by the Clinician Administered PTSD Scale (CAPS; Weathers, Ruscio, & Keane, 1999). The OQ includes three subscales: symptom distress, interpersonal relations, and social role functioning and was developed as a measure of progress in therapy. Phase II also included a brief self-report measure—the Dimensions of Anger (DAR; Forbes et al., 2004), administered biweekly. Diagnostic interviews conducted during the pre-treatment assessment included the CAPS and the Structured Clinical Interview for DSM-IV (SCID-I; Spitzer et al., 1995).

Results: Phase I

During phase I we recruited an additional 4 participants beyond our original target of 8 CBI cases to provide sufficient experience. Two SI cases started treatment, as planned. Of the 12 CBI participants, 8 completed and 4 were non-completers. Two of the non-completers dropped due to high levels of anxiety, making it difficult to sit through sessions and focus on the material (both were referred for alternative treatment), one dropped for logistical reasons, and one failed to complete for unknown reasons. Of the two SI participants, one completed and one discontinued after 10 sessions due to obtaining a job. Post treatment assessments were completed for the 8 CBI and 1 SI completers; 3 month follow up assessments were conducted for 6 CBI participants.

Preliminary findings from Phase I were promising for the 8 participants who completed treatment. Pre to post treatment effect sizes on two of the STAXI-2 anger expression scales (anger expression out and anger control out) were in the moderate to large range: .54 and .83 respectively. Pretreatment to follow-up effect sizes on the same two scales were .83 and 1.0. Large effect sizes were also found on the OAS-M scales ranging from 1.1 to 2.9.

Results: Phase II

Thirty-two veterans were assessed for eligibility during Phase II; 7 of these were not randomized. Four were excluded due to recently starting on medication or desiring other treatment, one was unexpectedly redeployed, one decided not to participate, and did not respond to further contacts for unknown reasons. Of 25 randomized, two did not enter treatment. One lost interest, and one was redeployed. Twenty-three participants began treatment, including 12 in CBI and 11 in SI. Demographics for the sample beginning treatment are shown in table 1. The two

conditions look similar on most features, with the exception of occupation where the CBI condition has a higher proportion of individuals with professional / technical / managerial occupation and the SI condition a higher proportion of Laborer / Craftsman / Clerical.

Table 1: Demographic Characteristics by Treatment Condition (Phase II)

	CBI (n=12)	SI (n=11)	All
Age: X (SD)	39.1 (10.2)	37.1 (10.8)	38.1 (10.5)
Sex: male	12 (100%)	11 (100%)	23 (100%)
Race/ethnicity			
Caucasian	11 (92%)	10 (91%)	21 (91%)
African American	1 (8%)	1 (9%)	2 (9%)
Hispanic	1 (8%)	0	1 (4%)
Marital Status			
Married/live Together	8 (67%)	7 (64%)	15 (65%)
Single	2 (17%)	4 (36%)	6 (26%)
Divorced	1 (8%)	0	1 (4%)
Education			
High school or GED	5 (42%)	7 (64%)	12 (52%)
Some college	4 (33%)	3 (27%)	7 (30%)
College or Post grad	3 (25%)	1 (9%)	4 (17%)
Occupation			
Unemployed	0	1 (9%)	1 (4%)
Laborer/ clerical	3 (25%)	8 (73%)	11 (48%)
Professional /technical	9 (75%)	2 (18%)	11 (48%)

Of the 23 participants entering treatment, 14 (61%) had at least 9 sessions. The average number of sessions for CBI was 8.92 (SD=4.9) and for SI was 9.18 (SD=5.4). Of those not completing the full 14 sessions, 4 reported feeling better and not needing more treatment, 2 were redeployed, 2 reported logistical problems, 2 stopped because of lack of improvement, and 2 dropped for unknown reasons. Failure to complete treatment that may conservatively be considered as negatively treatment – related (i.e. including logistical problems and unknown reasons in addition to failure to improve and failure to comply), is 26%, including 4 (33%) of CBI and 2 (18%) of SI. Post-treatment assessments were completed for 16 (70%) participants, including 8 for CBI and 8 for SI. Three month follow-up assessments were completed for 12 participants (6 in each condition).

Outcome Measures

Pre to Post-Treatment: Mean scores and ANOVA treatment effects for pre to post treatment on the STAXI-2 and the OAS-M are shown in table 2. (Means at the 3 month follow-up, discussed below, are also included in table 2). CBI showed more improvement than SI on the two primary outcome scales. The difference across conditions was significant ($p<.05$) on the STAXI-2 Anger Expression Index ($p=.019$),

and was close to significance on the OAS-M aggression scale (p=.059). All of the four scales that comprise the Anger Expression Index showed a similar pattern, with CBI differing significantly from SI. Between group effect sizes ranged from .98 to 1.22. Of the two other scales examined on the OAS-M, the total score was close to significantly better for CBI (p = .053), while the irritability score (not shown) did not differ significantly between CBI and SI.

Table 2: Means and ANOVAs: OAS-M and STAXI-II

	CBI Pretx X (SD)	**CBI** Posttx X (SD)	**CBI** Follup X (SD)	**SI** Pretx X (SD)	**SI** Posttx X (SD)	**SI** Follup X (SD)	ANOVA[4] (Pre to posttx) F p
STAXI-2	N=8	N=8	N=6	N=7[1]	N=7[1]	N=6	
Anger Expression Index	49.7 (10.5)	38.3 (11.1)	32.5 (9.9)	52.1 (9.7)	51.0 (11.6)	42.8 (19.6)	**7.6 .019**
Expression In[2]	19.9 (3.8)	15.3 (5.2)	16.8 (5.0)	19.6 (4.5)	20.3 (5.6)	16.8 (4.9)	9.9 .004
Expression Out[2]	18.6 (5.2)	15.2 (5.2)	13.3 (2.2)	18.7 (5.2)	20.7 (6.0)	17.2 (5.2)	24.0 < .001
Control In[3]	18.9 (5.2)	25.0 (6.8)	22.5 (6.2)	17.0 (4.5)	17.7 (6.7)	20.8 (6.9)	5.7 .034
Control Out[3]	17.8 (3.1)	23.4 (6.8)	23.2 (4.7)	17.1 (3.1)	16.6 (3.6)	18.3 (3.7)	6.0 .031
OAS-M	N=8	N=8	N=6	N=8	N=8	N=6	
Aggression Score	24.4 (17.2)	9.4 (10.1)	4.2 (2.0)	16.1 (12.8)	18.8 (13.7)	21.5 (24.2)	**4.28 .059**
Total Score	31.4 (19.0)	14.4 (11.8)	9.2 (3.6)	23.5 (13.2)	25.8 (15.6)	26.8 (26.5)	4.55 .053

[1]Missing data for one subject
[2]Lower scores better
[3]Higher scores better
[4]Treatment effect; pre-score as covariate

Table 3 shows effect sizes, including within treatment effect sizes for CBI and SI, and between group effect sizes. CBI showed large effect sizes from pre to post treatment on all except one of the measures. Between group effect sizes reflecting the greater improvement for CBI were also large.

Table 3: Pre – Post Treatment and Between Group Effect Sizes

	CBI Pre-post ES	SI Pre-post ES	Between group ES
STAXI-2	N=8	N=7	N=15
Anger Expression Index	1.04	0.10	1.12
Expression In	1.02	-0.14	1.13
Expression Out	0.65	-0.36	0.98
Control In	1.02[1]	0.12[1]	1.08[1]
Control Out	1.07[1]	-0.15[1]	1.22[1]
OAS-M			
Aggression Score	1.01	-.20	0.78
Total Score	1.08	-.16	0.82

[1]direction of effect size reversed for consistency

Results of ANOVAs examining pre to post treatment effects on the three subscales of a secondary measure (Outcomes Questionnaire) also showed superiority of CBI relative to SI (symptom distress scale: F=5.04, p = .043; interpersonal relationship scale: F=4.62, p=.051; and social role functioning: F=4.52, p=.053). Results of similar analyses for the CAPS total score, another secondary outcome measure (Table 4), did not show differences between the two groups, or show significant improvement within CBI (or SI). Analysis of the CAPS anger / irritability total score also did not show differences between CBI and SI, although each treatment showed significant pre to post treatment change on this item (Table 4).

Table 4: Means / SDs by treatment on CAPS total score and anger item

CAPS	CBI	Within tx t p	SI	Within tx t p	ANOVA[1] F p
Total score					
Pre tx	36.3 (12.4)		42.6 (18.4)		
Post tx	38.1 (15.0))	-1.68 NS	51.1 (28.3)	-0.42 NS	0.59 NS
Anger item					
Pre tx	5.6 (1.1)		6.6 (0.5)		
Post tx	4.4 (1.3)	3.0 .019	5.4 (1.9)	2.38 .049	.59 NS

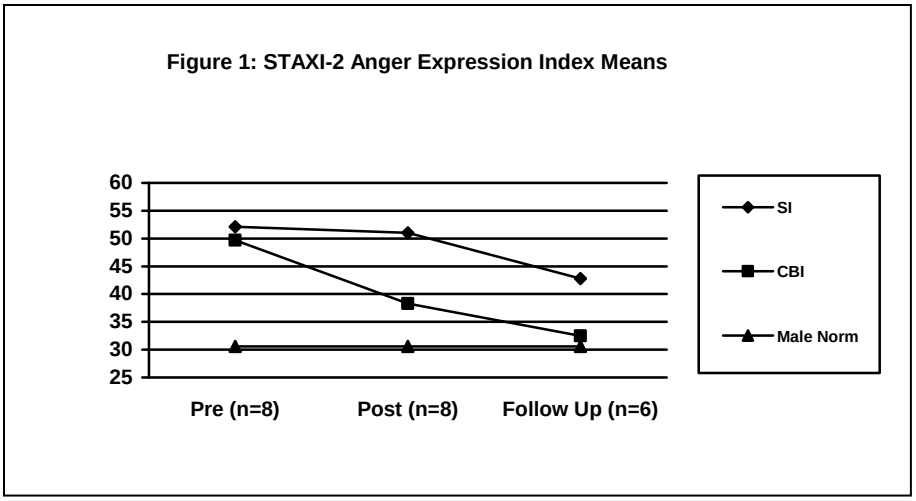
[1]Treatment effect, pre-score as covariate

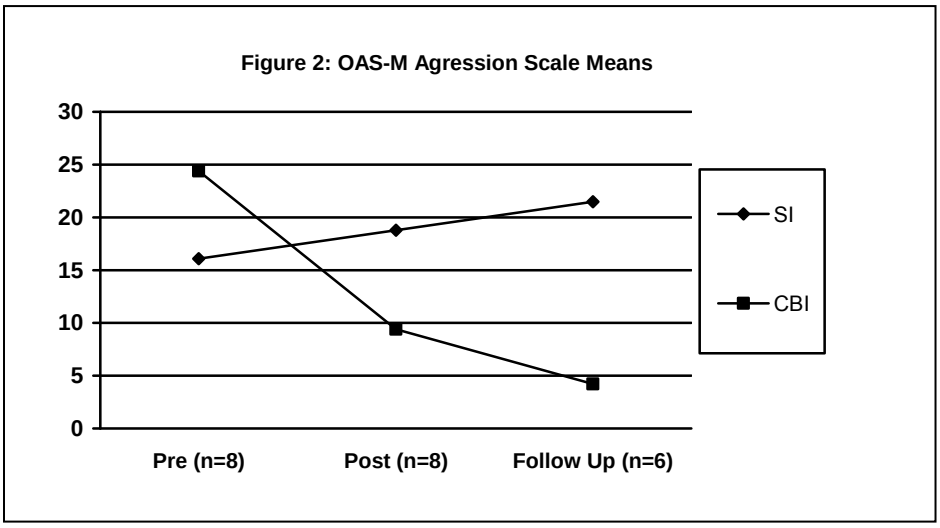
Of the 23 participants who began treatment, 7 did not complete post-treatment assessments. To provide a more complete picture of results we examined outcome using the last available score on the Dimensions of Anger Reactions (DAR) scale, which was administered bi-weekly (Table 5). Results of a univariate ANOVA with first administration scores included as a covariate showed significantly more improvement for CBI (F (1) = 5.66, p = .027).

Table 5: DAR means by treatment condition

	CBI (n=12)		SI (n=11)	
	X	SD	X	SD
N of administrations	4.83	(2.44)	4.88	(2.73)
First administration	13.58	(5.52)	15.09	(4.81)
Last administration	8.58	(5.96)	15.00	(7.56)
Mean change	5.00	(5.05)	0.09	(4.85)

Three month follow-up: The means for the 3 month follow-up assessments (table 2) show that the changes from pre to post treatment for CBI were largely maintained, and on some scales decreased further, at the 3 month follow-up. For SI, there was also some improvement between post-treatment and follow-up on the STAXI scales, but not on the OAS-M scales. Change from pre to post treatment and to 3 months post-treatment on the two primary outcome measures is illustrated in figures 1 and 2 below. As shown in figure 1, at the 3 month follow up, means for CBI were very close to normative means for normal males ages 30-39 (Spielberger, 1999).





Feasibility and Acceptability

One aspect of feasibility is the ability of therapists to implement the treatments according to the manuals. Sessions were rated on adherence measures designed for each of the two treatment conditions. A total of 72 sessions across 11 participants were rated for the CBI condition. At least one of the indicated interventions for the specific session rated was present for 71 of the 72 sessions rated (99%). Further analyses of the quality of the interventions are planned. Analyses of adherence in the SI sessions will also be conducted.

Seven CBI and 6 SI participants completed an evaluation of treatment form following treatment. For CBI, 5 reported being very satisfied and 2 moderately satisfied with treatment. Ratings for SI included 4 very satisfied, 1 moderately satisfied, and 1 neither satisfied nor dissatisfied. Thus all CBI and 5 of 6 SI participants appeared to be satisfied with the treatment they received. It is important to note that the absence of data on 10 participants who began treatment means that the satisfaction data is likely to be biased towards positive ratings.

Summary and limitations

The findings show that CBI resulted in more improvement than the control condition on multiple anger outcome measures. Differences were statistically significant or close to significance on all of the anger measures. One of these measures (OAS-M) is interview based, and was conducted by interviewers who were blind to treatment condition, reducing the likelihood of potential bias in ratings. An "intent to treat" analyses using the Dimensions of Anger scale that was completed at session 1 and biweekly thereafter, allowed inclusion of all participants entering treatment in the analysis. Finding superiority of CBI in this analysis reduces the possible effect of biased attrition, which can confound analyses of treatment completers. CBI also showed more improvement on our measure of functioning (the Outcome Questionnaire), suggesting that the effects were broader than the target of anger. CBI did not, however, show significant improvement or differ from SI on the CAPS PTSD total score. Although participants were not required to have PTSD to enter the study, PTSD symptoms were common, as reflected in a mean pretreatment score of 39.4 on the CAPS total score. Despite the improvement in anger, and improvement in some areas of functioning, CBI was not effective for other symptoms of PTSD. Improvement shown on the anger and outcomes questionnaire scales was maintained over 3 months of follow-up for those CBI participants completing the follow up assessment. It is of note that few studies have used a control condition as stringent as the current study—which included psychoeducation, arousal reduction training, and problem solving support in individual sessions 75 minutes in length. The average number of sessions completed was very similar in both conditions, increasing confidence in the acceptability and credibility of SI as a control condition. Of note is that CBI did not differ from SI in PTSD symptom change.

An important limitation of this research was the small sample size in Phase II. Although we exceeded our target in Phase I, we did not reach our target of 50 randomized subjects in Phase II. This is in part due to time lost when the original project director and two of our therapists were hired full time by the VA and unable to continue their role in the study. The study was without a doctoral level project coordinator for over a year and the study slipped in recruitment efforts. Recruitment was also delayed in order to have new therapists trained and ready to treat subjects. We also lost several potential subjects who were referred for pharmacotherapy and started on medications prior to being referred to the study. This highlights the need to adapt recruitment strategies in future studies to reach potential participants prior to medication referral (if clinically appropriate). The failure to reach our target would be more negative if we had not found positive results, given the reduction in statistical power. The effect sizes were sufficiently large to show significant differences in this small sample. A larger sample would nonetheless increase confidence in these early findings. A larger sample would also have allowed us to explore factors associated with nonresponse. Additionally, the study is limited by the absence of females, and by the small number of minority participants. Despite our attempts to recruit females, only one began treatment (Phase I) and dropped after the first session citing transportation and other logistical problems. Two additional potential female subjects who expressed interest did not start because of other demands. With regard to minorities, our sample included only 2 (9%) African Americans, and one Hispanic. These numbers largely reflect the population that most of our referrals came from (VA PTSD and other mental health clinics), which is largely male and Caucasian. It would be important for future research to include a sufficient number of female veterans and minorities to determine effects of CBI for a broader sample of OEF/OIF veterans.

A second limitation is that many participants did not complete treatment. Of 12 CBI participants entering treatment, 2 stopped early because they felt they no longer needed treatment, and one was redeployed. Two failed to comply or dropped for

unknown reasons, one failed to improve, and one cited logistical reasons (returning to school). Thus about 33% dropped for reasons that may reflect a negative response to the treatment. It may be that 14 weekly sessions is too long or unrealistic for some returning veterans with anger problems. Future studies might examine a reduced number of sessions.

Key Research Accomplishments

- The treatment adapted and studied for the treatment of anger in returning OEF/OIF veterans (CBI) showed moderate to large pre to post treatment effect sizes on anger measures in Phase I and Phase II of the research.
- Results of the randomized pilot study (Phase II) showed CBI to be significantly superior to an active control condition (Supportive Intervention, SI) on all measures of anger, and on scales assessing symptom distress and interpersonal and social functioning. Between group effect sizes were large on anger measures, ranging from .78 to 1.22.
- Improvement in CBI was maintained at the 3 month follow-up.
- There were no differences between CBI and the control in PTSD symptom change.
- Feasibility of training and implementation of the treatment was supported by adherence ratings of 72 audiotapes of CBI sessions by an independent doctoral level psychologist experience in cognitive behavioral interventions and PTSD in veterans.
- Ratings by a subgroup of participants suggested satisfaction with treatment.

Reportable Outcomes

Shea MT et al. Treatment of Trauma Related Anger in OIF veterans. Poster presented at the Military Health Research Forum, Kansas City MO, September 2, 2009.

Shea MT et al. Treatment of Trauma Related Anger in Troops Returning from Hazardous Deployments. Association for Behavioral and Cognitive Therapy Annual Meeting, Orlando FL, November 2008

Shea MT et al. Treatment of Trauma Related Anger in OIF/OEF Veterans. Society for Psychotherapy Research Annual Meeting, Barcelona, Spain, June 2008

Shea MT. Treatment of Anger Problems: Strategies and Effectiveness. Grand Rounds presentation. St. Luke's Hospital, New Bedford MA, February 2008.

Shea MT, Lambert JF, Sevin E, Howard J, Davis N. Treatment of PTSD-Related Anger in Troops Returning From Hazardous Deployments. Brown University 12th Annual Research Symposium on Mental Health Sciences, Providence RI, March 2008.

Shea MT, Lambert JF, Sevin E, Howard J, Davis N. Treatment of PTSD-Related Anger in Troops Returning From Hazardous Deployments. Poster presentation, International Society for Traumatic Stress Studies Annual Meeting, Baltimore MD, November 2007

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Conclusions

The research findings show support for the efficacy of an adapted cognitive behavioral intervention in the treatment of anger problems in OEF/OIF veterans. Findings need to be replicated in a larger scale clinical trial. Findings also need to be replicated in a sample including a sufficient proportion of females and minorities to determine efficacy for these groups. Future research might also address efficacy of a fewer number of sessions to increase applicability and feasibility on a larger scale. Problems with anger are common in veterans returning from Iraq and Afghanistan, including those with and without PTSD (Shea, unpublished data). Excessive anger and inability to effectively manage anger has been shown to have serious consequences in veteran samples, including divorce, employment difficulties, and violence, arrests and incarceration. An effective treatment provided early on following deployment in those having anger problems could have a critically important impact on the maintenance of family and other relationships, employment, and overall quality of life for these veterans and their families.

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